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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,591	09/03/2008	Jenneke Adriana Cadec	0470-062554	8519

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EXAMINER

ARCHIE, NINA

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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03/22/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@webblaw.com

Office Action Summary	Application No. 10/590,591	Applicant(s) CADEE ET AL.	
	Examiner NINA A. ARCHIE	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to Applicant's amendment and response filed 12-3-10. Claims 54-56 and 60-63 have been amended. Claims 68-71 are new. Claims 54-71 are pending and currently under examination.

Objections/Rejections Withdrawn

2. In view of the Applicant's amendments and remarks the following objections/rejections are withdrawn.

a) Rejection to claims 54-57 and 59-67 under 35 U.S.C. 102(b) as being anticipated by (Naidu et al WO/2000/72874A1) is withdrawn in light of applicant's amendment thereto.

b) Rejection to claims 54-67 under 35 U.S.C. 103(a) as being unpatentable over (Naidu et al WO/2000/72874A1) is withdrawn in light of applicant's amendment thereto.

New Grounds of Rejection

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 54-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naidu et al (WO/2000/72874A1 Date December 7, 2000) and Tomita et al (US Patent No. 5349024 Date August 23, 1994).

Naidu et al teach a method of preventing or inhibiting the growth of a microbe in or on a human subject, comprising: administering to a human subject a pharmaceutically

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acceptable composition by a pharmaceutically acceptable delivery route (see pg. 8 lines 20-35), wherein said composition is a pharmaceutically acceptable composition of matter comprising an aqueous buffer solution containing EDTA as a metal chelating agent and a physiologically acceptable salt and containing a mixture of native lactoferrin wherein said aqueous buffer solution having a pH between about 5.5 and about 7.5 (see claim 17, pg. 14 lines 24-30, and abstract). Naidu et al teach a non-systemic delivery route is useful for infections of the skin or externally accessible wounds (see pg. 24 lines 10-20). Naidu et al teach methods for reducing or inhibiting microbial contamination of a composition subject to microbial contamination, for example, a foodstuff, such as a meat product (e. g., a beef, pork or poultry product) (see pg. 28 lines 1-30). Naidu et al teach a method to treat product and thereby reduce or inhibit microbial contamination thereof (see claim 17 and pg. 28-30), which correlates to a method for decontamination of food products.

Naidu et al teach a method for inhibiting microbial growth in a foodstuff and inventive foodstuffs by employing the antimicrobial properties of lactoferrin, are useful alternative means of preventing food contamination and further teach said method intended for bacteriostatic food packaging or handling such as food containers comprising a material suitable for contact with food such as gloves or mitts utensils and for application for surfaces such as countertops, desks, chairs, etc. (see pg. 28-30 and pg. 31 lines 9-37), which correlates to a method for decontamination of inert surfaces. Naidu et al teach oral hygiene applications include the prevention or treatment of oral infections, plaque (e. g., caused by *Streptococcus mutans*), and periodontal diseases (e. g., caused by *Porphyromonas gingivalis*, *Prevotella intermedia*, or *Actinobacillus* (see pg. 15 lines 1-10). Naidu et al teach a delivery through the oral mucosa that can comprise an inner layer containing the therapeutic agent of choice, whereby the inner layer can have one surface adapted to contact and adhere to the moist mucosal tissue of the oral cavity and may have an opposing surface adhering to an overlying non-adhesive inert layer, wherein the inner layer can have one surface adapted to contact and adhere to the moist mucosal tissue of the oral cavity and may have an opposing surface adhering to an overlying non-adhesive inert layer (see pg. 15). Naidu et al teach mixtures of lactoferrin in an aqueous dispersion embodiment, from about 0.001% wt/vol to about 2.5% wt/vol, preferably from about

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0.5% wt/vol to about 2.0% wt/vol, most preferably about 1% wt/vol of LF, which correlates to a method, wherein the solution contains 0.2 to 20% (w/v) of lactoferrin (see pg. 13 lines 25-35). Naidu et al teach the composition contains a buffer system including a combination of a physiologically acceptable acid, such as ethylenediamine tetraacetic acid (EDTA), (which can be added in aqueous form or by gassing an aqueous solution or emulsion with carbon dioxide) (see pg. 14 lines 13-25), wherein the molar ranges of acid: base: salt is about (acid): 0.1 to 0.01M (base) which correlates to a method, wherein the solution contains 0.1 to 10 mM of EDTA. Naidu et al teach a method of preventing or inhibiting the growth of a microbe using said compositions in cleaners, soaps, etc. on surfaces such as bed stands in hospital settings for the prevention of nosocomial infection, which correlates to a method, wherein the inert surfaces.

Naidu et al is silent with regard to surgical instruments. Naidu et al does not teach a solution comprising lactoferrin having a pH below 3 in a method for wound care; oral care. Naidu et al does not teach a solution comprising lactoferrin having a pH below 3 in a method for decontamination of inert surfaces. Naidu et al does not teach a solution comprising lactoferrin having a pH below 3 in a method for decontamination of food products. Naidu et al does not teach a method, wherein the inert surfaces comprise surgical instruments.

The limitation in independent claims 54-57 and dependent claims 58-71 recite the limitation, "a solution comprising lactoferrin having a pH below 3". Although the reference of Naidu et al does not specifically teach the specific pH below 3 as claimed by applicant. The pH of a specific value is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal extracellular pH in order to best achieve the desired results. Thus, absent some demonstration of unexpected

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results from the claimed parameters, this optimization of pH value would have been obvious at the time of applicant's invention.

Furthermore, a particular parameter must first be recognized as a result-effective variable, i.e., a variable, which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Thus optimization of general conditions is a routine practice that would be obvious for a person in the art to employ.

It would have been obvious to one of skill in the art to modify the method, wherein the inert surfaces (as disclosed by Naidu et al) to incorporate a solution comprising lactoferrin having a pH below 3 in said methods because Tomita et al teach the heating of lactoferrins under acidic conditions with a pH under conditions between 1.0-6.5 maintains the physiological activities of lactoferrins such as antibacterial activity, iron-binding activity and antigenicity (see columns 1-2 and claims).

It would have been equally obvious to one of skill in the art to modify the method, wherein the inert surfaces (as disclosed by Naidu et al) to incorporate the method to comprise surgical instruments because Naidu et al teach a method of preventing or inhibiting the growth of a microbe using said compositions in cleaners, soaps, etc. on surfaces such as bed stands in hospital settings for the prevention of nosocomial infection.

One would have a reasonable expectation of success because a methods using a composition comprising lactoferrin (as disclosed by Naidu et al) is well known in the art.

Conclusion

4. No claims are allowed.
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie

Examiner

GAU 1645

REM 3B31

/ROBERT A ZEMAN/

Primary Examiner, Art Unit 1645